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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,155	07/14/2003	Douglas T. Gjerde	P002.210	9520

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PHYNEXUS, INC.  
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EXAMINER
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RAMILLANO, LORE JANET

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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05/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/620,155	<b>Applicant(s)</b> GJERDE ET AL.	
	<b>Examiner</b> Lore Ramillano	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 25-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
:9/26/06,6/12/06,12/7/05,10/5/04,9/13/04,11/13/03,8/8/03.

## **DETAILED ACTION**

### **Election/Restrictions**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-24, drawn to a low dead volume extraction column, classified in class 436, subclass 178.
  - II. Claim 25-34, drawn to a method for extracting an analyte from a sample solution, classified in class 210, subclass 638.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus, such as a Pasteur pipette.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Sue Kalman on 4/4/07 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-24. Affirmation of this election must be made by applicant in replying to this Office action.

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Claims 25-34 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### **Claim Rejections - 35 USC § 112**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is rejected because it is unclear what applicant means by claiming that the claimed "first engaging end receives the second engaging end *in a telescoping relation.*"

### **Claim Rejections - 35 USC § 103**

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 1, 2, 6, 9, 10, 14, 15, and 22-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stefkovich (US 5368729) in view of Dorval et al. ("Dorval," US 5547833).

Stefkovich discloses an extraction column comprising: a column body having an open end, an open lower end, and an open channel between the upper and lower end of the column body; a bottom frit bonded to and extending across the open channel, the bottom frit having a low pore volume; a top frit bonded to and extending across the open channel between the bottom frit and the open upper end of the column body, and top frit having a low pore volume; the top frit, bottom frit, and channel surface define an extraction media chamber; and a bed of extraction media positioned inside the extraction media chamber (i.e. Fig. 1).

Stefkovich further discloses that the bottom frit is located at the open lower end of the column body (Fig. 1); the extraction media comprises a packed bed of gel-type packing material (i.e. column 3, lines 1-3); the bottom frit is a membrane screen and the top frit is a membrane screen, which comprises a polymeric material (i.e. column 2, lines 65-68); the column body comprises polypropylene (i.e. column 2, lines 58-60); first and second membrane filters are bonded to the column body by welding (i.e. column 2, lines 46-57); a lower tubular member comprising the lower end of the column body, a first engaging end, and a lower open channel between the lower end of the column

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body and the first engaging end; and an upper tubular member comprising the upper end of the column body, a second engaging end, and an upper open channel between the upper end of the column body and the second engaging end, the top membrane screen of the extraction column bonded to and extending across the upper open channel at the second engaging end, wherein the first engaging end engages the second engaging end to form a sealing engagement (i.e. Fig. 1); and the first end has a tapered bore (Fig. 1).

Stefkovich does not specifically disclose a frit less than 350 or 200 microns thick. Dorval discloses a radial flow assay apparatus comprising filters having a thickness of from about 50 microns to about 300 microns (i.e. column 3, lines 1-4). It would have been obvious to a person of ordinary skill in the art to modify Stefkovich by incorporating Dorval's filter, which has a thickness of about 50 microns, to enhance the selectivity of components to be filtered through the column.

11. **Claims 1-3, 6-13, 16, 18, 19, and 20-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ngo et al. ("Ngo," US 5219529) and Dorval.

Ngo discloses an extraction column comprising: a column body having an open end, an open lower end, and an open channel between the upper and lower end of the column body; a bottom frit bonded to and extending across the open channel, the bottom frit having a low pore volume; a top frit bonded to and extending across the open channel between the bottom frit and the open upper end of the column body, and top frit having a low pore volume; the top frit, bottom frit, and channel surface define an extraction media chamber; and a bed of extraction media positioned inside the extraction media chamber (i.e. Figs. 1-4).

Ngo further discloses that the bottom frit is located at the open lower end of the column body (Fig. 1); the extraction media comprises a packed bed of gel-type packing material, which is agarose (i.e. column 4, line 46 to column 5, line 20); the bed of extraction media has a bed volume of less than 20 microliters (i.e. column 2, lines 61-69); the extraction media comprises a gel-type chromatography bead (i.e. column 4, line 46 to column 5, line 20); the extraction media comprises an affinity binding group, such as Protein A (i.e. column 4, line 46 to column 5, line 20); the column body comprises a syringe (Fig. 1); the bottom frit is a membrane screen and the top frit is a membrane screen, which comprises a polymeric material (i.e. column 3, line 55 to column 4, line 29); a lower tubular member comprising the lower end of the column body, a first engaging end, and a lower open channel between the lower end of the column body and the first engaging end; and an upper tubular member comprising the upper end of the column body, a second engaging end, and an upper open channel between the upper end of the column body and the second engaging end, the top membrane screen of the extraction column bonded to and extending across the upper open channel at the second engaging end, wherein the first engaging end engages the second engaging end to form a sealing engagement (i.e. Figs. 1-4); and the first end has a tapered bore (Fig. 1).

Ngo does not specifically disclose a frit less than 350 or 200 microns thick, and a pump, such as a peristaltic pump.

Dorval discloses a radial flow assay apparatus comprising filters having a thickness of from about 50 microns to about 300 microns and a peristaltic pump for purifying the analyte (i.e. column 3, lines 1-4; column 23, lines 49-59). It would have

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been obvious to a person of ordinary skill in the art to modify Ngo by incorporating Dorval's filter, which has a thickness of about 50 microns, to enhance the selectivity of components to be filtered through the column. In addition, it would have been obvious to a person of ordinary skill in the art to modify Ngo by having Dorval's peristaltic pump because it would be desirable to create a faster and more convenient method of passing the fluid through the syringe and column.

12. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ngo and Dorval, as applied to claims 1-3, 6-13, 16, 18, 19, and 20-24 above, and further in view of Ichikawa et al. ("Ichikawa," US 4708800).

Ngo in view of Dorval does not specifically disclose a frit with a pore volume of 0.5 microliters or less (or 10% or less).

Ichikawa discloses a porous hollow fiber membrane comprising filters, which have a porosity in the range of 5 to 60% (i.e. column 2, lines 39-62). It would have been obvious to a person of ordinary skill in the art to modify Ngo in view of Dorval by having filters with a pore volume of 0.5 microliters or less (or 10% or less) because it would be convenient to have a filter that ensures a specific amount of fluid passes through the filter at one moment.

13. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ngo and Dorval, as applied to claims 1-3, 6-13, 16, 18, 19, and 20-24 above, and further in view of Becker et al. ("Becker," US 4308204).

Ngo in view of Dorval does not specifically disclose a bed of extraction media having a dry weight of less than 10 mgs.

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Becker discloses a process for isolating or purifying a component from blood by utilizing an adsorbent such as agarose, which has a dry weight of 8 grams (i.e. column 3, lines 19-35). It would have been obvious to a person of ordinary skill in the art to modify Ngo in view of Dorval by having agarose, which has a dry weight of less than 10 mgs, to ensure that a sufficient amount of extraction media is present in the column to isolate or purify the analyte of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano  
Examiner  
Art Unit 1743

  
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